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REISSUE APPLICATION DECLARATION BY THE INVENTOR

Docket Number (Optional)

PROV1100-1

As a below named inventor, I hereby declare that:

My residence, mailing address and citizenship are stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is described and claimed in patent number 6,037,366, granted March 14, 2000, and for which a reissue patent is sought on the invention entitled COMPOSITION FOR CREATING VASCULAR OCCLUSIONS

the specification of which

☒ is attached hereto.

☐ was filed on _____ as reissue application number _____ / _____

and was amended on _____
(If applicable)

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I verily believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below. (Check all boxes that apply.)

☐ by reason of a defective specification or drawing.

☒ by reason of the patentee claiming more or less than he had the right to claim in the patent.

☐ by reason of other errors.

At least one error upon which reissue is based is described below. If the reissue is a broadening reissue, such must be stated with an explanation as to the nature of the broadening:

See attached Reissue Application Declaration by the Inventor of Robert E. Krall (4 pgs.), Charles W. Kerber (4 pgs.) and Kimberly Knox (4 pgs.)

[Page 1 of 2]

Burden Hour Statement: This form is estimated to take 0.5 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

(REISSUE APPLICATION DECLARATION BY THE INVENTOR, page 2)

Docket Number (Optional)

~~XXXXXX~~ PROV1100-1

All errors corrected in this reissue application arose without any deceptive intention on the part of the applicant. As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the United States Patent and Trademark Office connected therewith.

Name(s)

Lisa A. Haile, J.D., Ph.D.

Registration Number

38,347

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed.

Full name of sole or first inventor (given name, family name)

Robert E. Krall

Inventor's signature

Robert E. Krall

Dates

3/22/01

Residence

2728 Via Dieguenos, Alpine, California 91901

Citizenship

United States

Mailing Address

Same

Full name of second joint inventor (given name, family name)

Charles W. Kerber

Inventor's signature

Charles W. Kerber

Dates

22 Mar 2001

Residence

4444 Tapa Tapa Drive, La Mesa, California 91941-7160

Citizenship

United States

Mailing Address

Full name of second third inventor (given name, family name)

Kimberly Knox

Inventor's signature

Kimberly Knox

Dates

3/23/01

Residence

4444 Tapa Tapa Drive, La Mesa, California 91941-7160

Citizenship

United States

Mailing Address

☐ Additional joint inventors are named on separately numbered sheets attached hereto.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Name of Patentees: Krall et al.
Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS

BOX REISSUE

Commissioner for Patents
Washington, D.C. 20231

REISSUE APPLICATION DECLARATION BY
THE INVENTOR ROBERT E. KRALL

I, Robert E. Krall hereby declare as follows:

- 1) My residence is: 2728 Via Dieguenos, Alpine, CA 91901
- 2) I am a citizen of the United States of America
- 3) I have been an employee of Prohold Medical Technologies, Inc., now Provasis
Therapeutics, Inc., since Sept. 1995.

4) On about February 15, 2001, I became aware that the claims of issued U.S.Pat.
No. 6,037,366 render that patent partly inoperative because we claimed less in that patent than
we had the right to claim.

5) Amended and new claims to U.S.Pat. No. 6,037,366 are set forth in this reissue
application submission. These claims are supported by the specification and contain matter that
we were entitled to claim originally. The new claims do not contain any new matter.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Name of Patentees: Krall et al.
Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS
Krall Declaration
Page: 2

In independent claims 1 and 5, the ethyl myristate claimed as an element of the composition should have been more broadly claimed as "a fatty acid ester." The polymer of 2-hexylcyanoacrylate should read "stabilized," rather than "sterilized." Part 2 of the composition should not contain the language "a weak aqueous bicarbonate solution."

Ethyl myristate is a type of fatty acid ester. The specification discloses that, "any of the large chain fatty acid esters will work to replace ethyl myristate" (col. 2, lines 1-3. *See also* col. 3, lines 47-50). The broader class of fatty acid esters should have been claimed in the original claims to this invention.

In the specification, the polymer of part 2 of the composition is shown to be stabilized and sterilized simultaneously. (col. 2, lines 24-26.) The resulting polymer is stable. The polymer in this stable state was available to be claimed in the claims of the original application, but was not. Therefore the language describing the polymer of 2-hexyl cyanoacrylate should read "stabilized," rather than "sterilized."

The composition claimed in U.S.Pat. No. 6,037,366 includes the language "in a weak aqueous bicarbonate solution" with respect to part 2. As can be seen in column 2, lines 10-14, the weak aqueous bicarbonate solution is used in the preparation of the polymer that is part of the claimed composition. However, the weak aqueous bicarbonate solution is not itself an element

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Name of Patentees: Krall et al.
Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS
Krall Declaration
Page: 3

in claimed composition. Therefore, we are requesting removal of the language “in a weak aqueous bicarbonate solution” from claims 1 and 5.

The language of dependent claim 3 has been amended to reflect the changes in claims 1 and 2, from which it depends.

Additionally, in claim 5, part (b), the mixture does not necessarily have to be injected. Many methods of delivery are available. The specification of the present invention simply discusses “the delivered product,” (col. 2, lines 51-62) but not specific methods of delivery. Claim 5 has been broadened to recite “administering.”

In claim 5, the language “with the gold metal powder suspended in the mixture” has been deleted. While this is a characteristic disclosed in the specification, it is not necessary to the invention. Therefore that language has been removed from part (b) of claim 5.

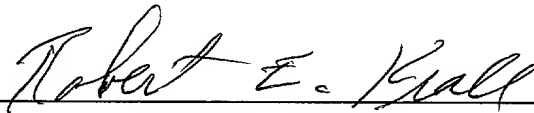
New claims 6 to 16 have been added. These claims provide further protection for the invention, but do not add any new matter. Independent claims 6 and 11 are directed to the previously unclaimed broad inventive concept of the invention, as set forth in the specification. Support for claim 6 can be found in the specification at, for example, col. 1, lines 59-61, col. 1, lines 66 to col. 2, line 4, col. 2, lines 24-26, and col. 3, lines 42-45. Support for claim 11 can be found in the specification at, for example, col. 1, lines 51-52, col. 1, line 59 to col. 2, line 3, and col. 2, lines 34-38. Dependent claims 7 to 10 and 12 to 16 are directed to additionally disclosed,

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

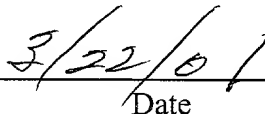
Name of Patentees: Krall et al.
Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS
Krall Declaration
Page: 4

but previously unclaimed, features of the broad inventive concept. These claims are supported by the specification. Support for claim 7 and 12 can be found in the specification at, for ex., col. 1, lines 64-65 and col. 3, lines 19-24. Support for claim 8 and 13 can be found in the specification at, for ex., col. 3, lines 42-45. Support for claims 9 and 15 can be found in the specification at, for example, col. 2, lines 34-36. Support for 10 and 14 can be found in the specification at, for example, col. 2, lines 1-3. Support for claim 16 can be found in the specification at, for example, col. 1, lines 50-51.

During the prosecution of the Application, the full scope of the invention as it relates to the elements of the claimed composition was not appreciated by me or my Attorneys. The claims as submitted in this reissue application more broadly and more fully claim the disclosed invention.



ROBERT E. KRALL



Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Name of Patentees: Krall et al.
Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS

BOX REISSUE

Commissioner for Patents
Washington, D.C. 20231

REISSUE APPLICATION DECLARATION BY
THE INVENTOR CHARLES W. KERBER

I, Charles W. Kerber hereby declare as follows:

- 1) My residence is: 4444 ^{Topa Topa 3/23/01 CK} ~~Tapa Tapa~~ Drive, La Mesa, CA 91941-7160.
- 2) I am a citizen of the United States of America
- 3) I have been an employee of Prohold Medical Technologies, Inc., now Provasis Therapeutics, Inc., since October, 1995.
- 4) On or about February 15, 2001, I became aware that the claims of issued U.S.Pat. No. 6,037,366 render that patent partly inoperative because we claimed less in that patent than we had the right to claim.
- 5) Amended and new claims to U.S.Pat. No. 6,037,366 are set forth in this reissue application submission. These claims are supported by the specification and contain matter that we were entitled to claim originally. The new claims do not contain any new matter.

In independent claims 1 and 5, the ethyl myristate claimed as an element of the composition should have been more broadly claimed as "a fatty acid ester." The polymer of 2-

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Name of Patentees: Krall et al.
Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS
Kerber Declaration
Page: 2

hexylcyanoacrylate should read "stabilized," rather than "sterilized." Part 2 of the composition should not contain the language "a weak aqueous bicarbonate solution."

Ethyl myristate is a type of fatty acid ester. The specification discloses that, "any of the large chain fatty acid esters will work to replace ethyl myristate" (col. 2, lines 1-3. *See also* col. 3, lines 47-50). The broader class of fatty acid esters should have been claimed in the original claims to this invention.

In the specification, the polymer of part 2 of the composition is shown to be stabilized and sterilized simultaneously. (col. 2, lines 24-26.) The resulting polymer is stable. The polymer in this stable state was available to be claimed in the claims of the original application, but was not. Therefore the language describing the polymer of 2-hexyl cyanoacrylate should read "stabilized," rather than "sterilized."

The composition claimed in U.S.Pat. No. 6,037,366 includes the language "in a weak aqueous bicarbonate solution" with respect to part 2. As can be seen in column 2, lines 10-14, the weak aqueous bicarbonate solution is used in the preparation of the polymer that is part of the claimed composition. However, the weak aqueous bicarbonate solution is not itself an element in the claimed composition. Therefore we are requesting removal of the language "in a weak aqueous bicarbonate solution" from claims 1 and 5.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Name of Patentees: Krall et al.
Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS
Kerber Declaration
Page: 3

The language of dependent claim 3 has been amended to reflect the changes in claims 1 and 2, from which it depends.

Additionally, in claim 5, part (b), the mixture does not necessarily have to be injected. Many methods of delivery are available. The specification of the present invention simply discusses "the delivered product," (col. 2, lines 51-62) but not specific methods of delivery. Claim 5 has been broadened to recite "administering."

In claim 5, the language "with the gold metal powder suspended in the mixture" has been deleted. While this is a characteristic disclosed in the specification, it is not necessary to the invention. Therefore that language has been removed from part (b) of claim 5.

New claims 6 to 16 have been added. These claims provide further protection for the invention, but do not add any new matter. Independent claims 6 and 11 are directed to the previously unclaimed broad inventive concept of the invention, as set forth in the specification. Support for claim 6 can be found in the specification at, for example, col. 1, lines 59-61, col. 1, lines 66 to col. 2, line 4, col. 2, lines 24-26, and col. 3, lines 42-45. Support for claim 11 can be found in the specification at, for example, col. 1, lines 51-52, col. 1, line 59 to col. 2, line 3, and col. 2, lines 34-38. Dependent claims 7 to 10 and 12 to 16 are directed to additionally disclosed, but previously unclaimed, features of the broad inventive concept. These claims are supported by the specification. Support for claim 7 and 12 can be found in the specification at, for ex., col.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Name of Patentees: Krall et al.
Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS
Kerber Declaration
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1, lines 64-65 and col. 3, lines 19-24. Support for claim 8 and 13 can be found in the specification at, for ex., col. 3, lines 42-45. Support for claims 9 and 15 can be found in the specification at, for example, col. 2, lines 34-36. Support for 10 and 14 can be found in the specification at, for example, col. 2, lines 1-3. Support for claim 16 can be found in the specification at, for example, col. 1, lines 50-51.

During the prosecution of the Application, the full scope of the invention as it relates to the elements of the claimed composition was not appreciated by me or my Attorneys. The claims as submitted in this reissue application more broadly and more fully claim the disclosed invention.



CHARLES W. KERBER



Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Name of Patentees: Krall et al.
Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS

BOX REISSUE

Commissioner for Patents
Washington, D.C. 20231

REISSUE APPLICATION DECLARATION BY
THE INVENTOR KIMBERLY KNOX

I, Kimberly Knox hereby declare as follows:

- Topa Topa UK 3/23/01*
- 1) My residence is: 4444 ~~Tapa-Tapa~~ Drive, La Mesa, CA 91941-7160.
 - 2) I am a citizen of the United States of America
 - 3) I have been an employee of Prohold Medical Technologies, Inc., now Provasis Therapeutics, Inc., since October, 1995.
 - 4) On or about February 15, 2001, I became aware that the claims of issued U.S.Pat. No. 6,037,366 render that patent partly inoperative because we claimed less in that patent than we had the right to claim.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Name of Patentees: Krall et al.
 Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
 Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS
 Knox Declaration
 Page: 2

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Name of Patentees: Krall et al.
Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS
Knox Declaration
Page: 3

The language of dependent claim 3 has been amended to reflect the changes in claims 1 and 2, from which it depends.

Additionally, in claim 5, part (b), the mixture does not necessarily have to be injected. Many methods of delivery are available. The specification of the present invention simply discusses "the delivered product," (col. 2, lines 51-62) but not specific methods of delivery. Claim 5 has been broadened to recite "administering."

In claim 5, the language "with the gold metal powder suspended in the mixture" has been deleted. While this is a characteristic disclosed in the specification, it is not necessary to the invention. Therefore that language has been removed from part (b) of claim 5.

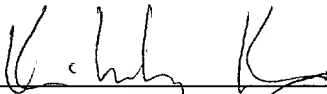
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Name of Patentees: Krall et al.
Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS
Knox Declaration
Page: 4

1, lines 64-65 and col. 3, lines 19-24. Support for claim 8 and 13 can be found in the specification at, for ex., col. 3, lines 42-45. Support for claims 9 and 15 can be found in the specification at, for example, col. 2, lines 34-36. Support for 10 and 14 can be found in the specification at, for example, col. 2, lines 1-3. Support for claim 16 can be found in the specification at, for example, col. 1, lines 50-51.

During the prosecution of the Application, the full scope of the invention as it relates to the elements of the claimed composition was not appreciated by me or my Attorneys. The claims as submitted in this reissue application more broadly and more fully claim the disclosed invention.



KIMBERLY KNOX

03/23/01

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Name of Patentees: Krall et al.
Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS

BOX REISSUE

Commissioner for Patents
Washington, D.C. 20231

POWER OF ATTORNEY BY ASSIGNEE

As a below-named assignee of the above-identified application ("Application"):

I hereby appoint the following attorneys of the assignee to prosecute the
Application and to transact all business in the United States Patent and Trademark Office
connected therewith:

TIM ELLIS
LISA A. HAILE
RICHARD J. IMBRA
SHEILA R. KIRSCHENBAUM
JUNE M. LEARN
TIMOTHY W. LOHSE
TERRANCE A. MEADOR
STEVEN R. SPRINKLE
BARRY N. YOUNG

Registration No. 41,734
Registration No. 38,347
Registration No. 37,643
Registration No. 44,835
Registration No. 31,238
Registration No. 35,255
Registration No. 30,298
Registration No. 40,825
Registration No. 27,744

Name of Patentees: Krall et al.
Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS
Page 2

I hereby authorize and request insertion of the application number of the
Application when officially known.

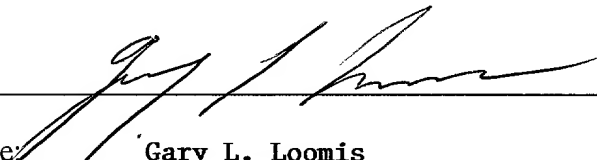
Direct all telephone calls to:

LISA A. HAILE, J.D., PH.D.
Telephone: (858) 677-1456

Address all correspondence to:

LISA A. HAILE, J.D., PH.D.
GRAY CARY WARE & FREIDENRICH LLP
4365 Executive Drive, Suite 1600
San Diego, CA 92121

PROVASIS THERAPUETICS, INC.

By: 
Name: Gary L. Loomis
Title: Vice President, Research & Development
Date: March 30, 2001

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**REISSUE APPLICATION: CONSENT OF ASSIGNEE;
STATEMENT OF NON-ASSIGNMENT**

Docket Number (Optional)

PROV1100-1

This is part of the application for a reissue patent based on the original patent identified below.

Name of Patentee(s) **Robert E. Krall, Charles W. Kerber, and Kimberly Knox**Patent Number **6,037,366**Date Patent Issued
March 14, 2000Title of Invention
COMPOSITION FOR CREATING VASCULAR OCCLUSIONS

1. ☒ Filed herein is a statement under 37 CFR 3.73(b). (Form PTO/SB/96)
2. ☐ Ownership of the patent is in the inventor(s), and no assignment of the patent is in effect.

One of boxes 1 or 2 above must be checked. If multiple assignees, complete this form for each assignee. If box 2 is checked, skip the next entry and go directly to "Name of Assignee".

The written consent of all assignees and inventors owning an undivided interest in the original patent is included in this application for reissue.

The assignee(s) owning an undivided interest in said original patent is/are **PROHOLD MEDICAL TECHNOLOGIES, INC.** and the assignee(s) consents to the accompanying application for reissue.

Name of assignee/inventor (if not assigned)

Signature

Date

3/30/01

Typed or printed name and title of person signing for assignee (if assigned)

Gary L. Loomis
Vice President, Research & Development

STATEMENT UNDER 37 CFR 3.73(b)Applicant/Patent Owner: Robert E. Krall, Charles W. Kerber, and Kimberly KnoxApplication No./Patent No.: 6,037,366 Filed/Issue Date: March 14, 2000Entitled: COMPOSITION FOR CREATING VASCULAR OCCLUSIONSPROVASIS THERAPEUTICS, INC., a Delaware corporation,

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest.
The extent (by, percentage) of its ownership interest is _____%

in the patent application/patent identified above by virtue of either:

- A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.
2. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.
3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

[] Additional documents in the chain of title are listed on a supplemental sheet.

- [☒] Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (i.e., the original assignment document or a true copy of the original document) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

March 30, 2001

Date

Gary L. Loomis

Typed or printed name

Signature

Vice President, Research & Development

Title